REMARKS

Claims 1-36 are pending in the application. Claims 1-36 have been cancelled herein without prejudice or disclaimer of the subject matter contained therein. New claims 37-79 have been added herein.

New claims 37-79 are generally based on original claims 1-36, which have been rewritten for clarity in U.S. claim format and to correct some typographical errors in order to expedite prosecution. Support for these amendments can be found in the original claims and throughout the specification. In particular, independent claim 1 has generally been rewritten as new claim 37, and independent claim 36 has generally been rewritten as new claims 77-79. Accordingly, Applicants submit that no new matter has been added by these amendments.

After entry of these amendments, claims 37-79 will be pending in the application.

Applicants hereby respond to the Office Action dated September 15, 2005, which detailed a Restriction Requirement under 35 U.S.C. § 121 and 372. In response to the restriction requirement, Applicants hereby elect Group I, claims 1-24 (now claims 37-67), drawn to a transdermal vaccine, with traverse.

Applicants contend that the subject matter of Groups I-III, including all of the pending claims, is highly related and relate to a single general inventive concept, which is the claimed transdermal vaccine.

The Office Action states that the "inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features . . . ." The Office Action cites Paul *et al.* and further states that the technical feature linking the inventions of groups I-III does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the art. Applicants respectfully disagree.

M.P.E.P. § 1850 states:

> If the common matter of the independent claims is well known and the remaining subject matter of each claim differs from that of the others without there being any unifying novel inventive concept common to all, then clearly there is lack of unity of invention. If, on the other hand, there is a single general inventive concept that appears novel and involves inventive step, then there is unity of invention and an objection of lack of unity does not arise. For determining the action to be taken by the examiner between these two extremes, rigid rules cannot be given and each case should be considered on its merits, the benefit of any doubt being given to the applicant. (Emphasis added)

Applicants submit that there is a single general inventive concept that at least appears novel and involves inventive step.

The claimed embodiments of the invention relate to a transdermal vaccine and various kits including the vaccine and methods of using the vaccine. As known to one of skill in the art, a vaccine confers a protective immune response and does not merely induce the production of antibodies. By way of nonlimiting example, Taber's Cyclopedic Medical Dictionary defines "vaccine" as a "suspension of infectious agents, or some part of them, given for the purpose of establishing resistance to an infectious disease . . . ." (page 2050, attached hereto as Appendix A).

In contrast, Paul *et al.* does not disclose a vaccine because the reference does not disclose a protective immune response to the formulations administered therein and in addition merely tests BSA and FITC, which would not be expected to induce a protective response. As discussed in the specification of the instant application, Paul *et al.* shows the induction of antibody titers for potent antigens that were comparable with those elicited by subcutaneous protein injections. (See specification, page 4, first full paragraph). However, as shown in FIG. 4 (see lower two panels on left hand side of figure) of the present application, the total antibody titer (or even specific antibody titer) does not necessarily correlate with survival. The description of FIG. 4 in the examples

further explains that the "data shown in figure 4, moreover, indicate that the absorbency of even the specific antibody titre is not a reliable predictor of the therapeutic, that is, of prophylactic effect of an epicutaneous vaccination. This is due to the big differences in specific antibody isotypes which only contain a substantial proportion of TH1-like IgG2b compared to Th2-like IgG1 component if sufficiently pure antigen is used . . . ." (Page 39, lines 3-7)

This fact is further stated in the specification at page 20, second full paragraph, which states that "it is important to realize that a high (specific) antibody titre does not necessarily imply a good protection result; to achieve the desired and sufficient protection the right kind and relative amount of certain antibody isotypes is required, such that will give prevalently Th1- or Th2-type of immune response" as the case should be. Paul *et al.* does not disclose that a prophylactic immune response can be elicited by using vaccines as claimed in the present application. For these reasons, Paul *et al.* do not disclose all of the limitations of the claimed invention and is not enabling for the claimed invention.

With regard to original claim 36, this claim has been rewritten generally as claims 77-79. Applicants submit that these amendments clarify that these claims encompass the same general inventive concept alleged to be lacking in original claim 36.

Thus, all three groups relate to a single inventive concept that is not disclosed by Paul *et al.* Accordingly, Applicants submit that there is a single general inventive concept that <u>at least appears</u> novel and involves inventive step.

Additionally, Applicants note that M.P.E.P. § 1893.03(d) states that the "unity of invention (not restriction) practice is applicable in international applications (both Chapter I and II) and in national stage applications submitted under 35 U.S.C. 371." Furthermore, M.P.E.P. § 1850 states that

> The method for determining unity of invention under PCT Rule 13 shall be construed as permitting, in particular, the inclusion of any

> one of the following combinations of claims of different categories in the same international application:
>
> (A) In addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product . . . .

Applicants note that Groups I-III are directed to a transdermal vaccine, a method of vaccinating using the vaccine from Group I, and a method for the preparation of a vaccine. Accordingly, Applicants submit that for this additional reason, the unity of invention rejection is inappropriate.

Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the Restriction Requirement.

The Office Action also alleges that the application contains claims directed to more than one species of the generic invention. Applicants understand from a telephone conversation with the Examiner that Applicants are being requested to choose one item within each of Species A, Species B, and Species C.

In response to the species requirement, with regard to Species A, Applicants hereby elect IL-12 (from original claim 8 now claim 45). With regard to Species B, Applicants hereby elect an antigen derived from pathogens triggering tetanus (from original claim 11 now claim 48). With regard to Species C, Applicants hereby elect surfactant-like molecules (from original claim 17 now claim 58).

The Office Action further requests that the reply identify the claims readable on the elected species. With regard to Species A (original claims 8-9 corresponding to new claims 45-46), there are no claims dependent on new claims 45-46. However, more generic claims 37-44 and 47-79, although not specifically reciting this species, are readable on the elected species from claim 45. With regard to Species B (original claims 10-12, 14-15, and 19 corresponding to new claims 47-49, 51-54, and 61), there are no claims dependent on new claims 47-49, 51-54, and 61. However, more generic claims 37-47 and 49-79, although not specifically reciting this species, are readable on the

elected species from claim 48. With regard to Species C (original claim 17 corresponding to new claims 56-58), claim 59 depends from new claim 58 and therefore is readable on it, although the subject matter of new claim 59 is also derived from original claim 17. However, more generic claims 37-57 and 60-79, although not specifically reciting this species, are readable on the elected species from claim 58.

Applicants note that as stated in the Office Action, upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim.

Further and favorable consideration of all the claims of record on the merits is respectfully requested.

CONCLUSIONS

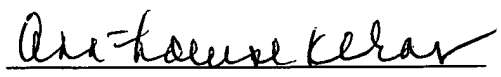
It is believed that all of the pending issues have been addressed. However, the absence of a reply to a specific rejection, issue, or comment does not signify agreement with, or concession of, that rejection, issue, or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, unless specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Applicants enclose herewith a Petition for a Five-Month Extension of Time up to and including March 15, 2006 to respond to this Restriction Requirement. Please charge our Deposit Account No. 08-0219 the $2160.00 fee for this extension.

Please also charge our Deposit Account No. 08-0219 the $350.00 fee for excess claim fees (7 unpaid for claims in excess of 20).

If the Examiner believes that any further discussion of this communication would be helpful, please contact the undersigned at the telephone number provided below.

Respectfully submitted,



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